

**Premarket Approval (PMA) Package for  
Dockets Management Branch**

**PMA Number P040018  
Docket # 2005M-0129**

**Bayer Healthcare, LLC  
ADVIA Centaur® HAV IgM ReadyPack Reagents  
and  
ADVIA Centaur® HAV IgM Quality Control  
Materials**

**Includes:**

**Approval Order  
Summary of Safety and Effectiveness Data (SSED)  
Labeling**

*2005M-0129*

*AAV 1*